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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STOCK JR, GORDON J

ART UNIT PAPER NUMBER

2877

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,571

Applicant(s)

MCCAFFREY ET AL.

Examiner

Gordon J Stock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6,9-11,13,14,23-27,29,34-36,39-42,44-56 and 62 is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,12,15-22,28,30-33,37,38,43 and 57-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 1-5, 7, 8, 12, 15-22, 57, 60, and 61** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, **claim 1 (claims 2-5, 7, 8, 12, 15-22 depend from claim 1)** has the limitation “a third sensor inside the housing for generating a door signal indicative of a closed door” and **claim 57 (claims 60-61 depend from claim 57)** has the limitation, “the door having a sensor for generating a door signal,” which was not described in the specification. The specification states software for detecting the door closure (page 16 paragraph 00066) and the paragraph 00061 on pages 14-15 discloses a microswitch for consumable presence. There is no suggestion that there is a separate sensor for door closure nor does the specification suggest that the software for door closure works with a ‘third sensor’ or even with the other two photodiode sensors.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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4. **Claims 1, 7, 12, 43, 57, and 61** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)** in view of **Wright et al. (WO 00/70011)**.

As for **claim 1**, Silver in a swabbing means and method in chemiluminescence discloses a housing for enclosing the sample in the absence of light; a first light sensor inside the housing; a second light sensor shielded from the luminescence by a LCD shutter and a controller that processes the signals (Figs. 1, 5a, 15; col. 21, lines 35-57; col. 22, lines 10-67). He is silent concerning a closeable door with a third sensor that generates a closed-door signal and the system being prevented from working without a closed door. However, Wright in a chemiluminescent system teaches having a system with a closeable door with a switch that signals the system that the door is closed in order to perform the measurement at a desired sample orientation (Fig. 1: 15, 50, 53; page 12, paragraph 3; page 4, paragraph 4). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have the housing have a closeable door with a sensor to signal a closed door in order to accurately measure the chemiluminescent material in the absence of external light and to have the luminescent reaction begin right at the time of the lid closing also to accurately measure the reaction without any delay, and the housing with the lid allows for non circular cross sectional containers to be receivable to maximize light collection.

As for **claim 7**, Silver in view of Wright disclose everything as above (see **claim 1**). In addition, Silver discloses a pair of analog to digital converters digitizing the sample and reference signals. The signals are conditioned (Fig. 15; col. 21, lines 35-57; col. 22, lines 10-67). And determination of dark noise suggests subtraction of signals (col. 23, lines 5-47).

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As for **claim 12**, Silver in view of Wright discloses everything as above (see **claim 1**). In addition, Silver discloses a window in the sample compartment that transmits light to the first sensor and another door, a hinged area, and a consumable (col. 7, lines 50-67; col. 8, lines 1-45; Fig. 5a).

As for **claims 43, 57, 61**, Silver discloses a housing provided with a sample compartment; a consumable collecting the sample and removably inserted into the sample compartment; a detection assembly located in the housing; a controller having multiple modes of operation; providing a first photodiode, a second photodiode, and a controller; comparing signals with a threshold; displaying the resulting signal indicative of the sample; detecting a consumable containing the sample in the sample compartment with a transparent bottom comprising a window (Figs. 1, 5a, 15; 9a-9c; col. 7, lines 50-67; col. 8, lines 1-45; col. 9, lines 1-20; col. 20, lines 5-25; col. 22, lines 5-67). Silver is silent concerning a closeable door with a third sensor that generates a closed-door signal and the system being prevented from working without a closed door. However, Wright in a chemiluminescent system teaches having a system with a closeable door with a switch that signals the system that the door is closed in order to perform the measurement at a desired sample orientation (Fig. 1: 15, 50, 53; page 12, paragraph 3; page 4, paragraph 4). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have the housing have a closeable door with a sensor to signal a closed door in order to accurately measure the chemiluminescent material in the absence of external light and to have the luminescent reaction begin right at the time of the lid closing also to accurately measure the reaction without any delay, and the housing with the lid allows for non circular cross sectional containers to be receivable to maximize light collection.

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5. **Claims 2-5, 22, 33, 38, 59, and 60** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)** in view of **Wright et al. (WO 00/70011)** further in view of **Taylor et al. (6,187,267)** and **Bryan (6,458,547)** and **Anderson et al. (4,818,883)**.

As for **claims 2-5, and 22**, Silver in view of Wright discloses everything as above (see **claim 1**). And for **claims 33 and 38**, Silver in view of Wright discloses everything as above (refer to **claims 57 and 30** above). In addition, Silver discloses integrators (Fig. 15) and that processing may be done serially or in parallel (col. 21, lines 35-55) and discloses integrators and temporal intervals for particular predetermined amounts to be detected (Fig. 15; col. 21, lines 35-57; col. 22, lines 10-67). As for solid state switching in capacitive circuits with particular time periods for detection, temperature, and capacitors, Silver is silent. However, Silver does teach by the integration and the intervals being performed. However, Bryan in a detection device teaches that capacitors with cycle intervals and comparisons between a measurement signal and a reference signal is used in determining concentrations of an analyte and that switched capacitive circuits are used for measuring concentrations (col. 41, lines 55-67; col. 42, lines 1-65). In addition, Taylor in a chemiluminescence device teaches the use of current integration mode in light detection using integration capacitors (col. 39, lines 25-50). And Anderson in a luminometer apparatus teaches that dark current may drift due to temperature (col. 1, lines 20-25). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have switched integrators with capacitors with particular time intervals in order to detect light and to determine concentrations of analyte in the chemiluminescent device. In addition, it would be obvious to one of ordinary skill in the art at the time the invention was

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made that a reference signal indicating temperature was present, for Silver's system took dark current readings which drift due to the dark current's dependence on temperature.

As for **claims 59-60**, Silver discloses generating a sample signal; generating a reference signal; integrating signals; digitizing signals; he suggests subtracting signals for calibrating may be done as well as dark current being found; integration periods, temporal intervals are used. (Fig. 15; col. 21, lines 35-57; col. 22, lines 10-67). He is silent concerning switched integrators with capacitors. Bryan in a detection device teaches that capacitors with cycle intervals and comparisons between a measurement signal and a reference signal is used in determining concentrations of an analyte and that switched capacitive circuits are used for measuring concentrations (col. 41, lines 55-67; col. 42, lines 1-65). In addition, Taylor in a chemiluminescence device teaches the use of current integration mode in light detection using integration capacitors (col. 39, lines 25-50). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have switched integrators with capacitors in order to detect light and to determine concentrations of analyte in the chemiluminescent device. As for responsive to temperature, he is silent. Anderson in a luminometer apparatus teaches that dark current may drift due to temperature (col. 1, lines 20-25). It would be obvious to one of ordinary skill in the art at the time the invention was made that a reference signal indicating temperature was present, for Silver's system took dark current readings which drift due to the dark current's dependence on temperature.

6. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al.** (6,372,511) in view of **Wright et al. (WO 00/70011)** further in view of **Wood (5,650,289)**.

As for **claim 8**, Silver in view of Wright disclose everything as above (see **claim 1**). As for calculating logarithmic number and displaying the log, Silver is silent. However, Wood in luciferase assay compositions teaches that there is a logarithmic relationship between luciferase concentration and light (Fig. 6). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have a logarithm calculated and displayed for luciferase concentration has a logarithmic relationship with light.

7. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)** in view of **Wright et al. (WO 00/70011)**.

As for **claim 15**, Silver in view of Wright disclose everything as above (see **claim 1**). As for three levels of intensity, Silver is silent. However, Wright in a luminometer system teaches having three levels of concentration range (Fig. 1: 61-63; page 13, paragraph 2). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have the system comprise three levels of intensity low, mid, high in order to display low, normal, and or abnormal levels of an analyte being tested.

8. **Claims 16-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)** in view of **Wright et al. (WO 00/70011)** further in view of **Ghaed et al. (5,700,427)**.

As for **claims 16-21**, Silver in view of Wright disclose everything as above (see **claim 15**). They are silent concerning an LED being turned on and off at predetermined times for comparison to predetermined levels of intensity: low, mid, and high. However, Ghaed in an apparatus for luminescent measurements teaches including an LED for testing the detector's performance (Fig. 25; col. 26, lines 1-20). Therefore, it would be obvious to one of ordinary

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skill in the art at the time the invention was made to have a reference LED in order to test performance of the photodetectors. And it would be obvious to one of ordinary skill in the art at the time the invention was made to have the LED have three different levels of illumination to test the photodetector at the three levels of detection range: low, mid, and high.

9. **Claim 28** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)** in view of **Taylor et al. (6,187,267)**.

As for **claim 28**, Silver in a swabbing means and method in chemiluminescence discloses a housing for enclosing the sample in the absence of light; a first light sensor inside the housing; a second light sensor shielded from the luminescence by a LCD shutter and a controller that processes the signals (Figs. 1, 5a, 15; col. 21, lines 35-57; col. 22, lines 10-67). In addition, Silver discloses window in the sample compartment and a door, a hinged area, and a consumable (col. 7, lines 50-67; col. 8, lines 1-45; Fig. 5a). He is silent concerning a pair of opposed planoconvex lenses. However, Taylor in a chemiluminescence detection device teaches using a pair of opposed planoconvex lenses, 117c and 117b, between the sample, 126, and a window, an aperture 131, in order to focus the sample's light to the detector (Fig. 5). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have the system comprise two opposed planoconvex lenses between the sample and a window in order to direct chemiluminescent light to the detector. As for the window being electroconductive, Silver is silent concerning the LCD shutter's makeup. However, it is well-known that LCD's comprise electroconductive plastic. Therefore, it would be obvious to one skilled in the art that the LCD shutter comprised an electroconductive plastic, for electro-conductive plastic provide charge conduction to provide the display in a LCD.

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10. **Claims 30, 32, 37, and 58** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)** in view of **Wright et al. (WO 00/70011)**.

As for **claims 30, 32, 37 and 58**, Silver discloses the following: a housing provided with a sample compartment; a detection assembly inside the housing; a transparent window, a LCD shutter, a controller inside the housing for determining whether a resulting signal processed is indicative of the sample; a consumable removably inserted in the sample compartment; a predetermined threshold; a display device (Figs. 1, 5a, 15; 9a-9c; col. 7, lines 50-67; col. 8, lines 1-45; col. 9, lines 1-20; col. 20, lines 5-25; col. 22, lines 5-67). He is silent concerning a housing with a closeable door and that the system prevents itself from operating unless the door is closed. However, Wright in a chemiluminescent system teaches having a system with a closeable door with a switch that signals the system that the door is closed in order to perform the measurement at a desired sample orientation when the door is closed (Fig. 1: 15, 50, 53; page 12, paragraph 3; page 4, paragraph 4). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have the housing have a closeable door with a sensor to signal a closed door in order to accurately measure the chemiluminescent material in the absence of external light and to have the luminescent reaction begin right at the time of the lid closing also to accurately measure the reaction without any delay, and the housing with the lid allows for non circular cross sectional containers to be receivable to maximize light collection.

As for a conductive film on the LCD shutter comprising indium tin oxide or a plastic, Silver is silent. However, it is well known in the art that liquid crystals comprise indium tin oxide and/or conductive plastic layers. Therefore, it would be obvious to one skilled in the art

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that the LCD shutter comprises indium tin oxide and/or conductive plastic, for indium tin oxide and/or conductive plastic layers provide charge conduction to provide the display in a LCD.

11. **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Silver et al. (6,372,511)** in view of **Wright et al. (WO 00/70011)** further in view of **Liljestrand et al. (6,200,531)**.

As for **claim 31**, Silver in view of Wright disclose everything as above (see **claim 30**). Silver is silent concerning a conductive chassis. However, Liljestrand in an apparatus for luminescent measurements teaches having a conductive chassis in order to protect the system from external environmental variations (col. 24, lines 8-20). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have the chassis be conductive in order to shield the system from external environmental variations.

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. In addition, Examiner apologizes for the inconvenience in reference to the indication of allowable subject matter in **claim 14 and 28** in the previous action but upon further search the Examiner found grounds of rejection for **claim 28** and prior art to reject the particular allowable subject matter of **claim 14**. In addition, with the arguments of August 2, 2004, the term, 'hand-held assay device,' in the claims has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951).

Allowable Subject Matter

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13. **Claims 6, 9-11, 13, 14, 23-27, 29, 34-36, 39-42, 44-56, and 62** are allowed.

As to **claim 6**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a hand held device the particular software, in combination with the rest of the limitations of **claim 6**.

As to **claim 9**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a handheld device “a calibration mode, wherein the cleanliness of the window is controlled” in combination with the rest of the limitations of **claim 9-11; 23-27**.

As to **claim 13**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a hand held assay device, “a LED pressed into a peripheral wall of the sample compartment” in combination with the rest of the limitations of **claims 13-14**.

As to **claim 29**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a hand held assay device, software for determining the presence of holes in the door in combination with the rest of the limitations of **claim 29**.

As to **claim 34**, the prior art of record, taken alone or in combination, fails to disclose or render obvious handheld assay device “a bandpass filter” in combination with the rest of the limitations of **claim 34**.

As to **claim 35**, the prior art of record, taken alone or in combination, fails to disclose or render obvious handheld assay device “a bandpass filter” in combination with the rest of the limitations of **claim 35**.

As to **claim 36**, the prior art of record, taken alone or in combination, fails to disclose or render obvious handheld assay device “a calibration value indicative of the cleanliness of the transparent window” in combination with the rest of the limitations of **claim 36**.

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As to **claim 39**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a handheld device “the detection assembly generating a calibration signal indicating cleanliness of the transparent window” in combination with the rest of the limitations of **claims 39-42, 44-49, and 51-56**.

As to **claim 50**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a handheld assay device the first, second, and third modes, in combination with the rest of the limitations of **claim 50**.

As to **claim 62**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a method of measuring the presence of a sample “the step of determining the cleanliness of the transparent bottom before determining the resulting signal” in combination with the rest of the limitations of **claim 62**.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

GB 2281966 A to Johnson et al. (specifically, Figs. 1 and 2)

U.S. Patent 6,103,534 to Stenger et al. (specifically, Fig. 2: 11)

U.S. Patent 6,509,195 to De Rooij et al. (specifically, Fig. 4: 14)

Fax/Telephone Numbers

If the applicant wishes to send a fax dealing with either a proposed amendment or a discussion with a phone interview, then the fax should:

1) Contain either a statement “DRAFT” or “PROPOSED AMENDMENT” on the fax cover sheet; and

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2) Should be unsigned by the attorney or agent.

This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The form of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CP4 Fax Machine number is: (703) 872-9306

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon J. Stock whose telephone number is (571) 272-2431.

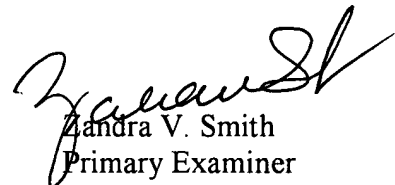
The examiner can normally be reached on Monday-Friday, 10:00 a.m. - 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr., can be reached at 571-272-2800 ext 77.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



gs
October 8, 2004



Sandra V. Smith
Primary Examiner
Art Unit 2877